

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (original) A crystalline imatinib mesylate form H1, characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 9.9, 11.1, 16.3, 17.3, 18.1, 19.1, 19.6, 20.3, 21.1, 21.9, 23.2, 23.6, 24.2, 24.9, 25.6, 26.0, 27.3, 27.9, 28.9, 29.4, 30.4 and 30.5 degrees.
2. (currently amended) A The crystalline imatinib mesylate form H1 as defined in claim 1, further characterized by a x-ray powder diffraction spectrum as in figure 1.
3. (original) A process for preparation of imatinib mesylate form H1 as defined in claim 1, which comprises the steps of:
 - a) dissolving imatinib free base in a chlorinated solvent;
 - b) adding methanesulfonic acid; and
 - c) isolating imatinib mesylate form H1 by filtration or centrifugation;
wherein the chlorinated solvents is selected from chloroform, methylene dichloride, ethylene dichloride and a mixture thereof.
4. (currently amended) A The process according to claim 3, wherein the chlorinated solvent is chloroform.
5. (currently amended) A The process according to claim 3, wherein the chlorinated solvent is methylene dichloride.

6. (original) A process for preparation of imatinib mesylate form H1 as defined in claim 1, which comprises the steps of:

- a) mixing imatinib mesylate and a chlorinated solvent; and
- b) isolating imatinib mesylate form H1 by filtration or centrifugation;

wherein the chlorinated solvent is selected from chloroform, methylene dichloride, ethylene dichloride and a mixture thereof.

7. (currently amended) ~~A~~ The process according to claim 6, wherein the chlorinated solvent is chloroform.

8. (currently amended) ~~A~~ The process according to claim 6, wherein the chlorinated solvent is methylene dichloride.

9. (original) Imatinib mesylate hydrate.

10. (currently amended) Imatinib mesylate hydrate of claim 9, wherein water content of the hydrate of imatinib mesylate is between about 2.0 to about 3.2% by weight of hydrate of imatinib mesylate.

11. (currently amended) Imatinib mesylate hydrate of claim 10, wherein water content of the hydrate of imatinib mesylate is between about 2.2 to about 2.9% by weight of hydrate of imatinib mesylate.

12. (original) Imatinib mesylate hydrate of claim 11, wherein water content of the hydrate of imatinib mesylate is about 2.5% by weight of hydrate of imatinib mesylate.

13. (original) A process for preparation of imatinib mesylate hydrate of claim 9, which comprises the steps of:

- a) dissolving imatinib mesylate in a mixture of a suitable solvent and water;

- b) removing the solvents from the solution formed in (a) either by vacuum drying or by spray drying;
wherein the suitable solvent is selected from alcohols, ketones, acetonitrile and a mixture thereof.
14. (currently amended) A The process according to claim 13, wherein the solvent is removed by vacuum drying.
15. (currently amended) A The process according to claim 13, wherein the solvent is removed by spray drying.
16. (currently amended) A The process according to claim 13, wherein the alcohol is selected from methanol, ethanol and isopropyl alcohol; and the ketone is acetone.
17. (currently amended) A The process according to claim 13, wherein the suitable solvent is methanol.
18. (currently amended) A The process according to claim 13, wherein the suitable solvent is ethanol.
19. (original) Amorphous imatinib mesylate hydrate.
20. (original) Amorphous imatinib mesylate hydrate of claim 19 characterized by a x-ray powder diffraction spectrum as in figure 2.
21. (original) Amorphous imatinib mesylate hydrate of claim 19, produced according to the process described in claim 13.

National Stage of PCT/IN03/00206
Attorney Docket No. H1089/2023
Preliminary Amendment Dated December 16, 2004

22. (original) A pharmaceutical composition comprising imatinib mesylate form H1 of claim 1 and a pharmaceutically acceptable carrier or diluent.
23. (original) A pharmaceutical composition comprising imatinib mesylate hydrate of claim 9 and a pharmaceutically acceptable carrier or diluent.
24. (original) A pharmaceutical composition comprising amorphous imatinib mesylate hydrate of claim 19 and a pharmaceutically acceptable carrier or diluent.